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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,701	02/08/2002	David Z. Lubowski	5804.02	2673

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DORSEY & WHITNEY, LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
370 SEVENTEENTH STREET  
SUITE 4700  
DENVER, CO 80202-5647

EXAMINER

LEUBECKER, JOHN P

ART UNIT PAPER NUMBER

3739

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/071,701

Applicant(s)

LUBOWSKI, DAVID Z. 

Examiner

John P. Leubecker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-10 and 12-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 and 12-42 is/are rejected.
- 7) ☒ Claim(s) 25-27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 6, 2004 has been entered.

***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on July 6, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Drawings***

3. The drawings were received on July 6, 2004. These drawings are acceptable.

***Claim Objections***

4. Claim 28 is objected to because of the following informalities: term "reusable" should be deleted for consistent claim terminology (the insufflation means is not previously described as being "reusable"). Appropriate correction is required.

***Specification***

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5. The amendment filed July 6, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the contamination prevention means (as originally disclosed) are not disclosed as (and are not capable of) isolating the illumination source from the insufflation means suffusing the lumen, as added to the paragraph spanning pages 17 and 18. The only element that is capable of providing this "isolation" is the window (14) in the embodiment shown in Figure 2 or the optical coupling means shown in Figure 15, for example.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As to claim 41, the newly added recitation stating that the contamination prevention means is “adapted to isolate the light source from the lumen” is not supported by the disclosure. The contamination prevention means, which is described as, for example, a one-way valve, filter or tortuous path (page 12, line 20 to page 13, line 8 and page 18, line 17 to page 19, line 3) is capable of isolating the insufflation means from the lumen and, in turn, the light source from the insufflation means (since the insufflation means would be isolated from the lumen, anything associated with the lumen would inherently and effectively be isolated from the insufflation means). However, the contamination prevention means, as disclosed, has nothing to do with whether or not the light source is isolated from the lumen. Such isolation appears to be accounted for by the window (14) in the embodiment shown in Figure 2 or the optical coupling means shown in Figure 15, for example.

As to claim 42, recitation that the contamination prevention means further comprises a gas-tight window is not consistent with the disclosure, as noted above. It appears that this claim should more properly read: the *connection means* further comprising a gas-tight window disposed between the lumen of the speculum and the light source.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2, 18-20 and 28-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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As to claim 2, this claim depends from a canceled claim (43). It appears that this claim should depend from claim 41, in which it will be assumed for examination purposes.

As to claims 18-20, these claims depend from a canceled claim (43).

As to claims 28-40, these claims are indefinite since the preamble improperly refers to a single element of the previous claim ("The disposable speculum"), making the scope of these claims unclear (e.g., as to which previously recited elements are encompassed by these claims). It appears that the preamble should read "A sigmoidoscope according to claim 41...".

As to claim 38, recitation of a "hollow tubular body" appears to be reciting an additional speculum tube (note claim 41 from which this claim depends recites a speculum having a substantially rigid tube). It appears that this claim should be further limiting the substantially rigid tube previously recited.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2, 3, 5-8, 10, 12-24, 28, 30, 31 and 33-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore (U.S. Pat. 3,889,661) in view of Sugiyama (Jap. Pub. No. 06-319691).

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Fiore discloses the device as described in detail in numbered paragraph 7 of the previous Office Action, paper number 9. Fiore also discloses conveying the insufflation medium directly from the insufflation means to the lumen by a gas conveying tube (34 and associated duct through annular part 26) without contacting the light source (25) as can be seen in Figure 1 (note col.6, line 63 to col.7, line 3). *Interpreting the contamination means as defined by the original specification for examination purposes*, Fiore fails to disclose a contamination means. However, Sugiyama teaches use of a contamination prevention means comprising a filter in the air feeding passage to prevent contaminated air from being fed into a body. It would have been obvious to one of ordinary skill in the art to have provided a filter in the air feeding pathway of the Fiore device for the reason taught by Sugiyama. It is noted that a filter which separates particles from a solution of air is considered a precipitator. Furthermore, the right angle between the lumen and the insufflation conduit (34) constitutes a "tortuous passageway". This tortuous passageway in combination with the added filter as taught by Sugiyama meet the limitations of claim 8.

12. Claims 9 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore in view of Sugiyama and further in view of Shiels (U.S. Pat. 5,061,239).

Fiore discloses a source air pressure (col.6, lines 60+) but fails to teach any particular means for providing such. One of ordinary skill in the art at the time the invention was made would have considered it obvious to use any known means for providing air pressure, including a squeeze bulb or even a mechanical air pump, since Fiore does not suggest that any particular type is required, Fiore does not suggest an example, and one of ordinary skill would have to draw from the prior art to "fill in the gaps" when reducing the Fiore device to practice. Shiels

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teaches that a squeeze bulb (3) can be used to supply air pressure to the body and is actually preferred over a mechanical pump (col.1, lines 30-34).

13. Claims 4, 6, 8, 9, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiore in view of Shiels.

As discussed above, Fiore fails to specifically disclose both a contamination prevention means comprising a non-return valve (e.g., one way valve) and a particular type of insufflation means (e.g., a squeeze bulb). However, for the same reasons set forth in numbered paragraph 11 above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the squeeze bulb of Shiels as the insufflation means in Fiore. Shiels also teaches use of a filter (col.3, line 60-65) and a one way valve (col.6, lines 7-12) as part of the insufflation means, both aiding in preventing contamination. Since it would be desirable to prevent contamination of the patient and the insufflation means, it would have been obvious to one of ordinary skill in the art, in view of the Shiels disclosure, to have provided either or both the filter and non return valve as taught by Shiels.

#### ***Allowable Subject Matter***

14. Claims 25-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***



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15. Applicant's arguments filed July 6, 2004 have been fully considered but they are not persuasive.

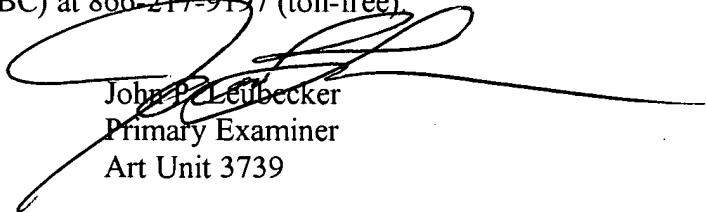
Applicant purports to amend claim 41 to include subject matter of previous claim 43 by including the language "insufflation medium being conveyed directly from the insufflation means to the lumen...without contacting the light source". This limitation never appeared in previous claim 43. Nonetheless, the Fiore disclosure meets this limitation. The conduit or slot of Fiore does not connect with or is not even close to the light source (lamps 25). This can clearly be seen in Figure 1.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (703) 308-0951. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P. Leubecker  
Primary Examiner  
Art Unit 3739

jpl